Reshaping Ventricle Curbs Mitral Regurgitation

BY MITCHEL L. ZOLER

FROM THE ANNUAL MEETING OF THE AMERICAN COLLEGE OF CARDIOLOGY

ATLANTA — A novel heart device safely cut the severity of functional mitral regurgitation and boosted patient survival compared with conventional mitral valve repair in a randomized, multicenter trial of 165 patients.

The Coapsys device is a durable, coated cord placed in a precise location through the center of a patient's left ventricle and held in place by two anchoring pads placed externally on opposite sides of the ventricle. Tension that the cord exerts on the pads reshapes the ventricle as well as the mitral annulus. The latter effect helps to partially correct the functional mitral regurgitation.

The study results "indicate that patients with functional mitral regurgitation requiring revascularization treated with ventricular reshaping rather than standard surgery had improved survival and significant reduction of major adverse outcomes," Dr. Eugene A. Grossi said at the meeting.

"By reshaping the ventricle, we cut the mortality to half of what was expected," a result that was "surprising," said Dr. Grossi, professor of cardiothoracic surgery at New York University. The results helped confirm the suspicion of many cardiologists and heart surgeons that functional mitral regurgitation is largely a disease of ventricular shape. The findings also indicate that "by treating the ventricle we'll be able to help these patients in addition to fixing" their mitral regurgitation.

"It's unfortunate that we don't have more tools to influence the ventricle," said Dr. Steven F. Bolling, professor of surgery and director of the mitral valve clinic at the University of Michigan, Ann Arbor.

The Randomized Evaluation of a Surgical Treatment for Off-Pump Repair of the Mitral Valve (RESTOR-MV) trial included 81 patients who received the Coapsys device plus coronary artery bypass grafting (CABG), and a control group of 75 patients treated by conventional mitral valve repair plus CABG and 9 patients treated with CABG alone. The device is placed on beating hearts without need for cardiopulmonary bypass. No patient had a perioperative, device-related complication. During 3-year follow-up, the incidence of all postoperative adverse events was 54% lower in patients treated with the Coapsys device compared with the controls, and the incidence of major postoperative adverse events—death, stroke, myocardial infarction, or need for a redo valve intervention—was 62% lower in the patients who received the Coapsys device. Both differences were statistically significant.

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Overall mortality was 15% in the Coapsys group and 30% in the control arm. In an analysis that adjusted for any baseline differences in patients, treatment with the Coapsys device cut overall mortality by 58% compared with all the control patients, a statistically significant difference. Survival was very similar during the first 3 months after surgery and then began to steadily diverge. "Mortality in the control arm was about the same as in any other trial of mitral valve repair in this kind of patient," Dr. Grossi said.

The average severity of mitral regurgitation in the 81 patients treated with the device fell from 2.40 (on a scale of 0-4) at baseline to an average of 1.25 24 months after surgery. Among the 75 control patients treated with mitral valve repair and CABG, regurgitation severity fell from an average score of 2.54 at baseline to 0.35 24 months after surgery. Although the control patients had a better average improvement in their regurgitation, the Coapsys patients had a significant improvement in their level compared with their baseline status. "We didn't do as good a job correcting the mitral regurgitation as standard mitral annuloplasty, but [the device] is a way to also treat the ventricle, and we all know that this is a ventricular disease," Dr. Grossi said.

Two years after surgery, the New York Heart Association heart failure rating of patients fell by at least one level in 79% of the patients treated with the Coapsys device and in 72% of the control patients, a difference that was not statistically significant. The average NYHA class heart failure level of patients entering surgery was 2.5. The average age of all study patients was 64 years; three-quarters were men.

The Coapsys device was easily implanted with a handheld echocardiography device for guidance, said Dr. Grossi, who placed the device in 40 patients.

Despite the promising results, future development of the device is unclear. Myocor, which developed the Coapsys device, went out of business while the study was in progress in 2008. Its intellectual property, including the concept behind the Coapsys device, was purchased by Edwards Lifesciences. A spokeswoman for Edwards declined to discuss plans for further development.

"Now knowing that we can take this approach to treating patients and help them with something as concrete as a mortality benefit, I think we'll see a lot of equivalent devices treating the ventricle and not the mitral valve alone," said Dr. Grossi, who had no disclosures relevant to the study. The study was sponsored by Myocor. ■

To view a video interview of Dr. Grossi, go to youtube.com/ElsGlobalMedicalNews and search for "Coapsys Heart Device."

MY TAKE

Study Leaves Questions Unanswered

Pure functional mitral regurgitation is probably responsible for about a third of all mitral regurgitation cases. We can identify functional mitral regurgitation by echocardiography. On echo, the mitral leaflets look normal but the valve has a central regurgitation because the annulus is distorted secondary to enlargement of the ventricle.

The Coapsys device is intended for patients at a relatively early stage of ventricular dilatation and moderate mitral regurgitation. One limitation of the trial is that it relied on current grading methods for mitral regurgitation severity, which are very imprecise.

The RESTOR-MV trial was underpowered. It serves as a demonstration study, and shows that the device has utility in some patients, but the study was not large enough or long enough to produce meaningful conclusions. It leaves unanswered several big questions, such as what happens to the patients' heart failure long term, and what occurs if patients require later heart surgery. How much scarring does the device cause, and will it allow subsequent valve repair?

In don't think that surgeons will favor placing such a device. It's imprecise. It reshapes the ventricle, but the heart ends up distorted and probably undergoes pericardial scarring. Questions remain about the device's impact on long-term ventricular and mitral valve function.

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Hydralazine/Isosorbide Dinitrate Cut Diastolic HF Mortality

BY BRUCE JANCIN

FROM THE ANNUAL MEETING OF THE AMERICAN COLLEGE OF CARDIOLOGY

ATLANTA — Treatment with hydralazine and isosorbide dinitrate was associated with a mortality benefit in both black and nonblack patients with diastolic heart failure in a large, retrospective, single-center study.

This is an encouraging, albeit nondefinitive, observation, since to date no treatment has been shown effective in decreasing mortality in patients with diastolic heart failure, Dr. Jeremy A. Mazurek noted at the meeting.

Because treatment with hydralazine and isosorbide dinitrate was shown to decrease mortality in black patients with systolic heart failure in the African-American Heart Failure Trial (N. Engl. J. Med. 2004; 351:2049-57), Dr. Mazurek wondered whether it might also be effective in the setting of diastolic heart failure, where there is a huge unmet need for medical therapies. He reviewed the last 10 years' experience with hydralazine/isosorbide dinitrate treatment in patients with diastolic heart failure at Montefiore Medical Center in New York.

The 1-year mortality was 16% in 949 black patients with diastolic heart failure who were treated with the drug compared with 21% in 4,053 who were not.

A significant reduction in mortality was also seen in nonblack patients with diastolic heart failure treated with hydralazine/isosorbide dinitrate, with a 1-year mortality rate of 25% in 634 patients compared with 32% in 5,866 nonblack patients not on the drug.

The limitation of this study is its nonrandomized, retrospective nature. Both black and nonblack diastolic heart failure patients who were placed on hydralazine/isosorbide dinitrate were significantly younger and more likely to be on beta-blocker therapy than were those who were not. On the other hand, they also had a higher prevalence of diabetes, prior MI, and cerebrovascular disease. In any case, these results provide justification for a definitive prospective randomized clinical trial of hydralazine/isosorbide dinitrate in the treatment of diastolic heart failure in patients of all races, according to Dr. Mazurek of Albert Einstein College of Medicine, New York.

He reported having no financial conflicts with regard to this retrospective study, which was conducted free of commercial support. ■